UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

ELEANOR FULGENZI
9828 Old Johnny Cake Ridge Rd.
Concord Twp., OH 44077

Plaintiff,

v.

WYETH, INC.
5 GIRALDA FARMS
MADISON, NJ 07940

and

WYETH PHARMACEUTICALS, INC.
500 ARCOLA ROAD
COLLEGEVILLE, PA 19426

and

SCHWARZ PHARMA, INC.
103 FOULK ROAD
WILMJNGTON, DE 19803

and

SCHWARZ PHARMA, INC.
D/B/A SCHWARZ
PHARMA,USA
103 FOULK ROAD

Case No.: 5:09 CV 1767

Judge: JUDGE LIOI

MAG. JUDGE PEARSON

WILMJNGTON, DE 19803 :
:
and :
:
SCHWARZ PHARMA, USA :
103 FOULK ROAD :
WILMINGTON, DE 19803 :
:
And :
:
PLIVA, INC. :
60 COLUMBIA ROAD :
MORRISTOWN, NJ 07960-4535 :
:
and :
:
TEVA PHARMACEAUTICALS, USA, INC.
CORPORATION TRUST CENTER :
1209 ORANGE STREET :
WILMINGTON, DE 19801 :
:
and :
:
ACTAVIS, INC., :
60 COLUMBIA ROAD :
MORRISTOWN, NJ 07960-4535 :
:
and :
:
ACTAVIS ELIZABETH, LLC :
200 ELMORA AVENUE :
ELIZABETH, N J 07202-1106 :
:
Defendants. :

COMPLAINT

COMES NOW, the plaintiff, **ELEANOR FULGENZI**, by and through her undersigned attorneys, states and alleges as follows:

I. PARTIES

1. **ELEANOR FULGENZI**, Plaintiff, (hereinafter referred to as "Plaintiff") is a resident of Lake County, Ohio. Plaintiff has resided in Lake County, Ohio since March of 2007. Prior to March 2007, Plaintiff resided in Summit County, Ohio.

2. Plaintiff brings this action for the purpose of recovering all damages allowable by law for personal injuries suffered as a result of **ELEANOR FULGENZI 'S** ingestion of Reglan/metoclopramide and/or metoclopramide HCI (hereinafter "Reglan/metociopramide").

The Defendants

3. Defendant, Wyeth, Inc., d/b/a Wyeth (hereinafter referred to as "WYETH") is a Delaware corporation with its principal place of business at 5 Giralda Farms, Madison, New Jersey, 07940.

4. References in this Complaint to "WYETH" include individually and collectively all divisions and/or subsidiaries, WYETH, as successor in interest to A.H. Robins, Inc., American Home Drugs Corporation, and ESI, Lederle, Inc.

5. At all times material hereto, WYETH was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, Reglan/metoclopramide in the State of West Virginia and in interstate commerce. WYETH may be served with process through its registered agent, Prentice Hall Corporation Systems, 830 Bear Tavern Road, Trenton, New Jersey, 08628. WYETH is subject to the jurisdiction and venue of this Court.

6. WYETH manufactures and distributes generic metoc1opramide through its ownership of ESI Lederle, Inc. (hereinafter referred to as "ESI"), a former subsidiary which merged into WYETH.

7. Defendant, Schwarz Pharma, Inc., (hereinafter referred to as "SCHWARZ") is a Delaware corporation, duly qualified to do business in the State of West Virginia with its principal place of business in Mequon, Wisconsin.

8. Defendant SCHWARZ, one of its predecessors in interest, and/or one of its families of wholly owned divisions was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, Reglan/metoclopramide in the State of West Virginia and in interstate commerce. SCHWARZ may be served with process through its registered agent, *CSC* Entity Services, LLC, 2711 Centerville Road, Wilmington, Delaware, 19808. SCHWARZ Pharma, Inc. is subject to the jurisdiction and venue ofth1s Court.

9. Defendant Pliva, Inc., (hereinafter referred to as "PLIVA") is a New York corporation with , its principal place of business in New Jersey. PLIVA is a wholly-owned subsidiary of PLIVA, d.d., which is wholly-owned subsidiary of Barr Pharmaceuticals, Inc. (hereinafter referred to as "BARR"). PLIVA may be served

with process through its registered agent: Corporation Trust Company, 820Bear Tavern Road, 3rd Floor, West Trenton, New Jersey, 08628. BARR is being sued herein as the owner of PLIVA and may be served with process through its registered agent: Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware, 19808. Hereafter, PLIVA and barr will be collectively referred to as "PLIVA."

10. At all times material hereto, PLIVA was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly through third parties or related entities, Reglan/metoclopramide in the State of West Virginia and in interstate commerce. PLIV A is subject to the jurisdiction and venue of this Court.

11. The Defendant, Teva Pharmaceuticals, USA, Inc., (hereinafter referred to as "TEVA") is a Delaware corporation with its principal place of business in Pennsylvania.

12. At all times material hereto, TEVA was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties or related entities, Reglan/metoc1opramide in the State of West Virginia and in interstate commerce. Teva may be served with process through its registered agent, the Corporation Trust Company, located at Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware, 19801. Teva is subject to the jurisdiction and venue of this Court.

13. Defendant, Actavis Elizabeth LLC, is a Delaware corporation with its principal place of business in New Jersey and is a wholly owned subsidiary of Actavis, Inc. Actavis, Inc. is the parent company with a business address of 60 Columbia Road, Morristown, New Jersey 07960· 4535 and may be served with process either at the aforementioned address and/or at 14 Commerce Drive, Suite 301, Cranford, New Jersey 07016. Hereafter, Actavis Elizabeth LLC and Actavis, Inc. will be collectively referred to as "Actavis".

14. At all material times Actavis was duly qualified to do business in the State of Pennsylvania and was engaged in the business of regularly testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties or related entities, Reglan/metocloprarnide in the State of Pennsylvania and the County of Philadelphia for which it derives significant and regular income.

15. Fictitious parties No.1 through 6 are party Defendants the identities of whom or which is otherwise known to Plaintiff at this time, but, whose true names will be substituted by amendment when the aforesaid lacking knowledge is ascertained.

16. Wyeth, Schwartz, Pliva, Teva, and Actavis identified *supra,* inclusive, and each of them, may be referred to in this complaint collectively as "MANUFACTURING DEFENDANTS."

17. At all relevant times, MANUFACTURING DEFENDANTS were acting by and through their agents, servants and/or employees, each of whom were acting within the scope and course of their employment by agency or authority on their behalf.

18. At all times relevant hereto, MANUFACTURING DEFENDANTS were in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising the pharmaceutical drugs known as Reglan/metoclopramide in the State of West Virginia and in interstate commerce.

II. VENUE AND JURISDICTION

19. Both jurisdiction and venue are proper in the Northern District of Ohio: The Defendants conduct or have conducted business activity in Summit County, Ohio and Lake County, Ohio and the Defendants have distributed products throughout Ohio. Plaintiff was prescribed, purchased and consumed the Defendants' products in the Northern District of Ohio.

20. Jurisdiction is based on complete diversity between the Plaintiff and all of the Defendants pursuant to 28 U.S.C. § 1332.

21. Venue is proper as to causes of action against all Defendants because:

    1. A substantial part of the cause of action accrued in the State of Ohio in that Plaintiff received and consumed the Defendants' pharmaceutical products in Lake County, Ohio (and/or Summit County, Ohio) and sustained injury in Lake County, Ohio (and/or Summit County, Ohio).
    2. All of the Defendants have directed their products into Lake County, Ohio (and/or Summit County, Ohio).
    3. All of the Defendants have sold their products in Lake County, Ohio (and/or Summit County, Ohio).
    4. Lake County, Ohio (and/or Summit County, Ohio) sits in the Northern District of Ohio, Eastern Division.

22. The amount in controversy exceeds $75,000.00.

III. FACTUAL BACKGROUND AND ALLEGATIONS

23. This case involves MANUFACTURING DEFENDANTS' failure to warn doctors and patients of information within its knowledge or possession or both, which indicated the subject Reglan/metoclopramide, when taken for long periods of time, caused serious, permanent, and debilitating side effects, including Tardive Dyskinesia and Akathisia.

24. MANUFACTURING DEFENDANTS jointly and severally, marketed, manufactured and distributed Reglan/metoclopramide and encouraged the long term. use of these drugs, misrepresented the effectiveness of these drugs and concealed the drug's dangerous side effects.

Reglan/Metoclopramide: Indications and Resulting Side Effects

25. Reglan/metoclopramide is indicated as short-term therapy for symptomatic gastroesophageal reflux and acute and recurrent diabetic gastric stasis.

26. Reglan/metoclopramide is indicated for use for no greater than twelve weeks; however, MANUFACTURING DEFENDANTS represented that Reglan/metoclopramide was safe for use to treat nausea and or esophageal reflux for durations that exceeded twelve weeks.

27. Patients who use metoc1opramide for a long period of time are at a significantly increased risk of developing a severe and permanent neurological movement disorder.

28. Other serious side effects caused by ingesting Reglan/metoclopramide for long periods of time include, but are not limited to, central nervous system disorders, depression with suicidal ideation, akathisia, tardive dyskinesia, tardive dystonia, visual disturbances, and interference with drug metabolism.

29. Patients who use Reglan/metoclopramide for long periods of time that are not able to effectively metabolize it are at a greater risk of developing these serious and permanent injuries.

30. Tardive Dyskinesia and Akathisia, are serious side effects associated with the ingestion of ReglanJmetoc1opramide, and are debilitating neurological disorders that often results in involuntary and uncontrollab1e movements of the head, neck, face, al111S, legs and trunk in addition to grotesque facial grimacing and open-mouthed, uncontrollable tongue movements, tongue thrusting, tongue chewing, and other involuntary movements.

31. Presently, .there is no cure for Tardive Dyskinesia or Akathisia.

Defendant Wyeth is Successor in Interest to Reglan's Innovator A.H. Robbins

32. Wyeth is the successor in interest to A.H. Robins Company, Inc., a Virginia corporation which first obtained approval by the United States Food and Drug Administration (hereinafter "FDA") to distribute metoclopramide, under the brand name "Reglan" under the FDA's New Drug Application (NDA)1 schema in 1983.

33. Defendant Wyeth's predecessor in interest, A.H. Ro bins Company, Inc. expressly warranted to some physicians that Reglan/metoc1opramide is safe in long-term use.

34. A.H. Robins knew that its warranties regarding safety for long term use would be relied upon by ordinary, reasonable, and prudent physicians who would share that information with other physicians in their community and that eventually physicians would come to rely on A.H. Robins' express warranties about Reglan/metoc1opramide's safety in long-term use.

35. A.H. Robins' express warranties about the safety ofReglan/metoc1opramide in long-term use were false and intentionally and negligently misleading.

36. As successor in interest to A.H. Robins Company, Inc., Wyeth is legally responsible for the conduct, fraudulent and negligent acts, intentional and willful omissions, and misleading representations and warranties made by A.H. Robins Company, Inc. concerning the safety and adequacy ofReglan/metoc1opramide, and all1iabilities stemming there from.

37. Wyeth manufactured, marketed and distributed Reglan, metoclopramide, and/or metoclopramide HCL through its Wyeth-Ayerst Laboratories Division in St. Davids, Pennsylvania and through its ownership of "ESI".

38. Wyeth knew that it must fully disclose material safety data and information regarding a new drug's chemistry, proposed manufacturing process, proposed model labeling, including warnings about risks and side effects, and test results involving animal studies, clinical studies, and the drug's bioavailability.

39. Wyeth knew that the data and information would be relied upon by the, medical community, Plaintiff's physician, Plaintiff and other like foreseeable users of Reglan/metoclopramide once the NDA was approved and Wyeth was listed as the Reference Listed Drug Company for the drug.

40. Wyeth intentionally and negligently disseminated misleading information to physicians' across the country, through a publication kno\VI1 as the *Physicians' Desk Reference* about the risks of long term ingestion of Reglan/metoclopramide and the increased risk of extrapyramidal side effects, including Tardive Dyskinesia, that patients were exposed to.

Defendant Schwarz Knowingly Acquired Metoclopramide's Risks

41. Defendant Schwarz purchased from Wyeth the rights and *liabilities* associated with Reglan/metoc1opramide, the terms of which, upon information and belief, obligated Schwarz to be responsible for claims related to the ingestion or use of Reglan/metoclopramide.

42. Defendant Schwarz entered into an indemnification agreement with Wyeth over the purchase of the innovator, Wyeth's, Reglan, which included disclosure of clinical studies on Reglan/metoclopramide that were not publicly available.

43. Because Defendant Schwarz acquired Defendant Wyeth's Reglan/metoclopramide assets and liabilities while Wyeth was involved in ongoing litigation regarding Reglan/metoclopramide, and nevertheless agreed to indemnify Wyeth against all claims related to the ingestion of the drug, Schwarz knew or should have known that the NDA label for Reglan/metoc1opramide (Wyeth's label) misrepresented the safety of the drug, withheld warnings of the known side effects of the drug, and knew or should have known of the safety issues surrounding it.

Defendants Wyeth & Schwarz's Failed to Act as Required by the FDA

44. Under the FDA schema, Wyeth was and is the Reference Listed Drug Company (RLD), under a specific NDA, for Reglan/metoclopramide.

45. Under the FDA schema, Defendant Schwarz was and remains the RLD and/or NDA holder for Reglan/metoclopramide.

46. At all times material hereto, Defendants Wyeth and Schwarz, as the FDA holder and/or RLD Company, were aware of the serious side effects caused by Reglan/metoclopramide including, but not limited to, central nervous system disorders, depression with suicidal ideation, akathisia, tardive dyskinesia, tardive dystonia, visual disturbances, and interference with drug metabolism.

47. Defendants Wyeth and Schwarz had a duty to ensure their warnings to the medical community are accurate and adequate, to conduct safety surveillance of adverse events for the drug, and to report *any* data related to the safety and/or accuracy of the warnings and information disseminated regarding the drug.

48. Defendants Wyeth and Schwarz represented that Reglanlmetoc1opramide was safe for use to treat gastritis/gastroesophageal reflux knowing that the drug was not safe for that purpose and was dangerous to the health and body of Plaintiff.

49. Defendants Wyeth and Schwarz represented that Reglan/metoclopramide caused minimal side effects of knowing that the drug causes central nervous system side effects, and extrapyramidal symptoms, among other side effects, far more frequently than represented.

50. Defendants Wyeth and Schwarz had actual knowledge, through their own studies and studies by independent investigators, that doctors frequently prescribed Reglan/metociopramide for long term use that was not safe for patients.

51. Defendants Wyeth and Schwarz had actual knowledge, through their own studies and studies by independent investigators, that nearly one-third of all patients who used Reglan/metoc1opramide received it on doctor's prescriptions for 12 months or longer, rather than 12 weeks or less.

52. Defendants Wyeth and Schwarz also had actual knowledge, through research by independent investigators, that the risk of Tardive Dyskinesia and other extrapyramidal side effects of Reglan/metoclopramide in patients who receive the drug for 12 weeks or longer is approximately 100 times greater than disclosed in package inserts for Reglan and the *Physicians Desk* Reference monograph for Reglan brand metoclopramide.

53. Defendants Wyeth and Schwarz knew, or through the exercise of reasonable care should have known, that many patients who use Reglan/metoclopramide are not able to effectively metabolize it and that as a foreseeable consequence of their inability to effectively metabolize, those patients have a greater risk of developing serious and permanent injuries.

54. Defendants Wyeth & Schwarz had actual knowledge of facts which demonstrated that representations in the Reglan/metoclopramide package insert, the PDR monograph, and literature they distributed concerning Reglan/metoclopramide to physicians were false and misleading.

55. Defendants Wyeth and Schwarz failed to correct their monograph and/or disclose that knowledge to the medical community, physicians, plaintiff, and other foreseeable users.

56. It is the public policy of the United States and of this state, as reflected in the Hatch-Waxman Act, to encourage the availability of cheaper, generic drug products that are therapeutically equivalent to name brand products and to encourage the substitution, as appropriate, of such generic products for name brand products in patients' medical therapy.

57. Defendants Wyeth and Schwarz; as prescription drug manufacturers and/or distributors, knew or ought to have realized that so-called "drug product selection laws," enacted in every state, including this state, authorize or require a prescription for a drug identified by product brand name or by generic name to be filled, subject to certain limited exceptions, with a generic drug product that is therapeutically equivalent to the name brand drug product.

58. Defendants Wyeth and Schwarz knew or ought to have realized that generic drug manufacturers customarily copy verbatim the package insert for the name brand prescription drug product to give the impression that the information contained in the package inserts accompanying their own generic prescription drug products is accurate and not misleading.

59. Defendants Wyeth and Schwarz knew or ought to have known that the generic drug manufacturers also typically rely upon the marketing efforts of the name brand manufacturer to generate sales of their own products.

60. Defendants Wyeth and Schwarz knew or ought to have realized that physicians commonly consult the information disseminated by the name brand manufacturer, in PDR monographs or otherwise, and rely upon that inforn1ation in their decisions concerning the prescribing of those products for their patients.

61. Defendants Wyeth and Schwarz knew or ought to have realized, specifically, that physicians would rely upon information disseminated to them by the name brand manufacturer, regardless of whether the prescriptions might be filled with either the name brand product, Reglan, or generic Reglan/metoclopramide, and that many patients, in accordance with those prescriptions, would be likely to ingest generic Reglan/metoclopramide.

Generic Defendants Failed to Act as Required by the FDA

62. Defendants Pliva and Fictitious Parties 1-6 each submitted an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration, based on representations made by the RLD Company, requesting permission to manufacture, market, and distribute generic Reglan/metoclopramide. All Defendants identified in this paragraph above, inclusive, and each of them, may be referred to in this complaint collectively as "GENERIC DEFENDANTS."

63. Under the ANDA process, the Code of Federal Regulations *required* the GENERIC DEFENDANTS to submit a label for Reglan/metoclopramide, initially identical in all material aspects to the reference listed drug label.

64. Under the Code of Federal Regulations, GENERIC DEFENDANTS had a duty to ensure their Reglan/metoc1opramide warnings to the medical community were accurate and adequate, to conduct post market safety surveillance, to review all adverse drug event information (ADE), and to report any information bearing on the risk and/or prevalence of side effects caused by Reglan/metoc1opramide.

65. Under the Code of Federal Regulations, if GENERIC DEFENDANTS discover information in the course of the fulfillment of their duties as outlined above, GENERIC DEFENDANTS must report that information to the medical community, Plaintiff s physician, Plaintiff and other foreseeable users of Reglan/metoclopramide to ensure that their warnings are continually accurate and adequate.

66. GENERIC DEFENDANTS failed to investigate the accuracy of its metoc1opramide and/or metoclopramide HCI drug label.

67. GENERIC DEFENDANTS failed to review the medical literature for the metoclopramide drug and/or metoc1opramide HCI drug.

68. GENERIC DEFENDANTS relied upon the name brand manufacturer and the reference listed drug company to review the aforementioned medical literature for Reglan/metoclopramide.

69. Under the FDA schema, if the FDA approves a label change as requested by an ANDA holder, the NDA holder (also referred to as the Reference Listed Drug Company) must also amend its label.

70. GENERIC DEFENDANTS failed to communicate the true and accurate risks and/or prevalence of severe neurological side effects resulting from the ingestion of drugs containing Reglan/metoclopramide.

MANUFACTURING DEFENDANTS
Failed to Meet Labeling & Package Insert Requirements

71. MANUFACTURING DEFENDANTS disseminated to physicians, through package inserts, the publication of a PDR monograph, and otherwise, infom1ation concerning the properties and effects ofReglan/metoc1oprarnide, with the intention that physicians would rely upon that information in their decisions concerning the prescription of drug therapy for their patients.

72. MANUFACTURING DEFENDANTS knew, or should have known through the exercise of reasonable care, that the package insert for Reglan/metoclopramide substantially understated the prevalence of acute and long term side effects of ingesting the drug.

73. MANUF ACTURING DEFENDANTS failed to use reasonable care to modify the package insert to adequately warn physicians about the true risks of both short term use and long term use, even after several injured patients filed lawsuits alleging inadequate warnings and produced competent expert testimony supporting their allegations.

74. MANUFACTURING DEFENDANTS owed a duty in all of their several undertakings, including the dissemination of information concerning Reglanin'letoc1opramide, to exercise reasonable care to ensure that they did not create unreasonable risks of personal injury to others.

MANUFACTURING DEFENDANTS Failed to Disclose Known, Serious Side Effects

75. Reglan/metoc1opramide was widely advertised by MANUFACTURING DEFENDANTS as a safe and effective treatment of diabetic gastroparesis, gastroesophageal reflux disease (GERD) and other gastrointestinal disorders.

76. MANUFACTURING DEFENDANTS failed to conduct and report post market safety surveillance on Reglan/metoclopramide.

77. MANUFACTURING DEFENDANTS failed to review all adverse drug event information (ADE) and to report any information bearing upon the adequacy and

accuracy of their warnings, efficacy', or safety, including the risks and/or prevalence of side effects caused by Reglan/metoclopramide.

78. MANUFACTURING DEFENDANTS failed to monitor all relevant scientific literature related to Reglan/metoclopramide.

79. MANUFACTURING DEFENDANTS failed to disclose material safety information regarding the serious and permanent ·side effects caused by taking Reglan/metoclopramide for long periods of time.

80. MANUFACTURING DEFENDANTS failed to report data, *regardless of the degree of significance,* regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan/metoclopramide.

81. MANUFACTURING DEFENDANTS knowingly concealed from physicians material facts bearing on the interpretation of package insert disclosures that exposure to Reglan/metoclopramide can lead to Tardive Dyskinesia and other ESP, that the risk is "believed" to increase with duration of therapy and total cumulative dose. and that therapy for longer than twelve (12) weeks "cannot be recommended."

82. MANUFACTURING DEFENDANTS concealed the fact that earlier false information disseminated by A.H. Robins Co., and/or Wyeth representing long term Reglan/metoclopramide therapy to be reasonably safe. was unscientific and false.

83. MANUFACTURING DEFENDANTS concealed the fact that Reglan/metoclopramide is a neuroleptic agent and dopamine antagonist, which can be expected to lead to Tardive Dyskinesia and other ESP with approximately the same high frequency, particularly in longer term use, as other neuroleptic drugs and those epidemiological studies have consistently confirmed this expectation.

84. MANUFACTURING DEFENDANTS also concealed the fact that the treatment of chronic or intermittent gastroesophageal reflux and/or diabetic gastroparesis, and/or other gastric disorders with Reglan/metoclopramide products for longer than 12 weeks is unlikely to be reasonably safe.

85. Some or all of the other MANUFACTURING DEFENDANTS, as a result of their participation as MANUFACTURING DEFENDANTS in previous litigation concerning Reglan and other Reglan, metoclopramide and/or metoclopramide HCI products, received clear notice of WYETH'S suppression of important safety information concerning Reglan, metoclopramide and/or metoclopramide HCI and their products, yet despite this notice chose to ignore the information and join consciously in the suppression.

86. Plaintiff's serious and permanent injuries, as described above, came about as a foreseeable and proximate result of the MANUFACTURING DEFENDANTS' dissemination of inaccurate, misleading, materially incomplete, false, and otherwise

inadequate information concerning the potential effects of exposure to and long term ingestion of Reglan/metoclopramide to the medical community, physicians, Plaintiff's physicians, Plaintiff and other foreseeable users of the drug.

IV. CAUSES OF ACTION

COUNT ONE
STRICT PRODUCTS LIABILITY

87. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this complaint with the same force and effect as if fully set forth herein.

88. MANUFACTURING DEFENDANTS developed, marketed and distributed Reglan/metoclopramide to the general public even after learning of the design, manufacturing, and side effect defects that threatened the foreseeable use of the drug

89. Reglan/metociopramide was defective and unreasonably dangerous and was expected to and did reach Plaintiff without substantial change in the drug.

90. MANUFACTURING DEFENDANTS had prior knowledge and information within their possession that indicated their Reglan/metoclopramide was dangerous and unreasonably capable of causing severe physical, mental and emotional injuries.

91. Despite such knowledge, MANUFACTURING DEFENDANTS knowingly and deliberately failed to warn the public, including Plaintiff, of the extreme risk of physical injury occasioned by the defects inherent in their Reglan/metoclopramide for the purpose of increasing profits and in order to advance their own pecuniary interests.

92. Reglan/metoclopramide was not reasonably safe as designed because the foreseeable risks involved in its use at the time the product left the possession of the MANUFACTURING DEFENDANTS clearly outweighed the utility of the product or its therapeutic benefits.

93. MANUFACTURING DEFENDANTS knew or should have known through testing, adverse event reporting, or otherwise, that the drug created a high risk of bodily injury and serious harm.

94. MANUFACTURING DEFENDANTS failed to provide timely and adequate warning or instructions regarding Reglan/metoclopramide with known design, manufacturing, and side effect defects.

95. MANUFACTURING DEFENDANTS failed to provide timely and adequate post-marketing warning or instruction because, after they knew or should have known of the risks of injury from Reglan/metoclopramide associated with long term use as

commonly prescribed, they failed to promptly respond to and adequately warn about these risks.

96. MANUFACTURING DEFENDANTS' Reglan/metoclopramide products are inherently dangerous for their intended use due to design and manufacturing defects and improper warnings of serious side effects. MANUFACTURING DEFENDANTS are therefore strictly liable to Plaintiff for damages.

COUNT 3
STRICT LIABILITY- MANUFACTURING DEFECT

97. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

98. MANUFACTURING DEFENDANTS were, at all times relevant hereto, in the business of selling Reglan/metoclopramide.

99. MANUFACTURING DEFENDANTS supplied, manufactured, labeled, distributed, and sold this product in an unreasonably dangerous condition. The product was defective and unreasonably dangerous at the time MANUFACTURING DEFENDANTS placed them in the stream of commerce.

100. The defects in the products were caused by the way the products were manufactured.

101. The nature of the defects resulting from the facts as described above are ones which Plaintiff was unable to detect, anticipate, or guard against.

102. MANUFACTURING DEFENDANTS' product at issue was in a defective condition unreasonably dangerous to the ordinary consumer, including Plaintiff, because Plaintiff could not anticipate the danger the products created.

103. The defective products were ingested into Plaintiff's body, and the bodies of others, in the manner intended by the manufacturer and in the same defective condition as when the products left the MANUFACTURING DEFENDANTS' control.

104. The defects in the product had a substantial part in causing the injuries to Plaintiff as described above.

105. As a proximate result, Plaintiff has suffered and will continue to suffer injury, harm, and economic loss as alleged herein, including a permanent and substantial physical disability, and expenses attributable to this disability.

COUNT 4
STRICT LIABILITY- DESIGN DEFECT

106. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

107. MANUFACTURING DEFENDANTS' Reglan/metoclopramide was defective because the foreseeable risks of pharmaceutical malfunction and failure outweigh the benefits associated with the drug.

108. Reglan/metoclopramide was expected to and did reach Plaintiff without substantial change or adjustment to its formulation upon ingestion.

109. MANUFACTURING DEFENDANTS, the manufacturer or supplier of Reglan/metoclopramide, knew or should have known of the design defects and the risks of serious bodily injury that exceeded the benefits associated with the formulation.

110. Furthermore, Reglan/metoclopramide and its design defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

111. Reglan/metociopramide manufactured or supplied to Plaintiff by MANUFACTURING DEFENDANTS were defectively designed due to inadequate warnings or instructions because the manufacturer knew or should have known through testing or otherwise that the products created a high risk of bodily injury and serious harm. MANUFACTURING DEFENDANTS failed to adequately and timely warn consumers of this risk.

112. As a direct and proximate result of MANUFACTURING DEFENDANTS' failure to warn and improper conduct, Plaintiff suffered and continues to suffer economic losses and other compensable injuries as alleged herein.

113. MANUFACTURING DEFENDANTS' Reglan/metoclopramide is a product inherently dangerous for its intended use due to design defects and improper warnings. MANUFACTURING DEFENDANTS are therefore strictly liable to Plaintiff for damages.

COUNTS
BREACH OF EXPRESS WARRANTY

114. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

115. MANUFACTURING DEFENDANTS' concealment and failure to warn through promotional statements and product literature expressly warranted to Plaintiff that Reglan/metoclopramide was safe and capable of treating gastrointestinal disorders, including diabetic gastroparesis, a long term chronic condition.

116. In response to these promises and express statements, Plaintiff and Plaintiff's physicians relied on such affirmations and warranties to Plaintiff through Plaintiff's physicians.

117. Reglan/metoclopramide does not conform to those express representations in light of recently discovered disclosures and information previously withheld by MANUFACTURING DEFENDANTS. MANUFACTURING DEFENDANTS' express warranty through its false statements failed to disclose and provide patient approval of the design, manufacturing, and safety defects inherent in the drug.

118. MANUFACTURING DEFENDANTS breached their warranty of the pharmaceutical soundness of Reglan/metoclopramide by continuing sales and marketing campaigns highlighting the safety of the drug, while they knew of the design, manufacturing and safety defects and risk of contracting a severe neurological disorder which was posed by use of the drug.

119. As a direct and proximate result of MANUFACTURING DEFEJ\TJ)ANTS' breach of their express warranty, Plaintiff suffered bodily and mental injury, harm, other compensable injury, and economic losses, compensable through this Court.

COUNT 6
BREACH OF IMPLIED W ARRANTIES

120. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

121. MANUFACTURING DEFENDANTS' concealment and failure to warn impliedly warranted the medical soundness of Reglan/metoclopramide by marketing, promoting, selling, and distributing the drug as achieving merchantable quality and as safe and fit for its intended use. MANUFACTURING DEFENDANTS further warranted Reglan/metoclopramide as able to perform and provide treatment of patients with symptomatic gastroesophageal reflux and acute and recurrent diabetic gastric stasis.

122. Plaintiff reasonably relied on the presumption that MANUFACTURING DEFENDANTS would provide notice, disclosure, or warnings of any risks associated with Reglan/metoclopramide's merchantability, quality, safety, and fitness for its intended use.

123. Contrary to such implied warranties, Reglan/metoclopramide was not of merchantable quality or safe or fit for its intended use, because the drugs were and are unreasonably dangerous and unfit for the ordinary, intended, and foreseeable use due to their adverse side effects.

124. MANUFACTURING DEFENDANTS knew that most physicians who prescribed Reglan/metoclopramide were not aware the drug is a dopamine antagonist and/or a neuroleptic agent, which is just as likely to cause serious extrapyramidal side effects as other dopamine antagonists and/or other neuroleptic drugs.

125. MANUFACTURING DEFENDANTS also knew that the risks of potentially irreversible neurological side effects when Reglan/metoc1opramide is used long term were much greater than most physicians realized. By failing to give adequate warnings about the dopamine antagonist and/or neuroleptic properties ofReg1an/metoclopramide and the risk of long term use that is associated with those properties, the MANUFACTURING DEFENDANTS breached implied warranties of merchantability and fitness for the ordinary use of Reglan/metoclopramide.

126. As a direct and proximate result of MANUFACTURING DEFENDANTS' breach of their implied warranties, Plaintiff suffered economic loss and other compensable injuries as alleged herein, and is therefore entitled to compensatory damages and equitable relief according to proof

COUNT 7
NEGLIGENCE

127. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

128. MANUFACTURING DEFENDANTS had a duty to exercise the care of an expert in all aspects of the formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, and sale of Reglan/metoclopramide to insure the safety of its drug and to insure that the consuming public, including the Plaintiff and Plaintiff's physicians and agents, obtained accurate information and instructions for the safe use or non-use of this drug.

129. MANUFACTURING DEFENDANTS failed to discharge this duty by distributing a defective drug into the stream of commerce without warning or notice of the foreseeable unreasonably dangerous side effects. MANUFACTURING DEFENDANTS' failure of duty exposed Plaintiff to a high risk of bodily injury and serious harm.

130. MANUFACTURING DEFENDANTS' breach of their duties proximately caused damages to Plaintiff. As a direct and proximate cause of MANUFACTURING DEFENDANTS' conduct. Plaintiff has suffered and will continue to suffer injury, harm, and economic loss as alleged herein, including a permanent and substantial physical disability, and expenses attributable to this disability. MANUFACTURING DEFENDANTS breached their duty with the understanding customers and physicians

would rely upon such actions when choosing MANUFACTURING DEFENDANTS' drug.

131. The MANUFACTURING DEFENDANTS were negligent and breached duties owed to Plaintiff with respect to metoclopramide in one or more of the following respects:

a) Despite knowledge of hazards and knowledge that the product was frequently prescribed for long teml use, they failed to accompany the product with adequate warnings and instructions regarding the adverse and long lasting side effects associated with the use of metoclopramide and particularly with foreseeable long term use; '"

b) They failed to conduct adequate testing;

c) Despite knowledge of hazards, they failed to conduct adequate post-marketing surveillance to determine the safety of the product;

d) Despite knowledge of hazards, they failed to adequately warn Plaintiff's physicians or Plaintiff that the use of metoclopramide could result in depression with suicidal ideation, akathisia, akinesia, tardive dyskinesia, tardive dystonia, visual disturbances and interferences with drug metabolism; and

e) Despite the fact that the MANUFACTURING DEFENDANTS knew or should have known that metoclopramide caused unreasonably dangerous side effects, they failed to adequately disclose the known or knowable risks associated with metoclopramide as set forth above; they willfully and deliberately failed to adequately disclose these risks, and in doing so, acted with a conscious disregard of Plaintiff's safety or welfare.

132. In the alternative, MANUFACTURING DEFENDANTS' acts of omissions and concealment of material facts of the foreseeable unreasonably dangerous side effects were made with the understanding patients and physicians would rely upon such statements when choosing MANUFACTURING DEFENDANTS' drug. Furthermore, the economic damages and physical harm caused by MANUFACTURING DEFENDANTS' conduct would not have occurred had MANUFACTURING DEFENDANTS exercised the high degree of care imposed upon it and Plaintiff therefore plead the doctrine of *res ipsa loquitur.*

COUNTS
NEGLIGENT MISREPRESENTATION

133. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

134. MANUFACTURING DEFENDANTS had actual knowledge of facts which demonstrated that representations in the Reglan/metoclopramide package inserts, the

PDR monograph, literature, and information in oral marketing plans or otherwise disseminated, promulgated and distributed to physicians and .the medical community were false and misleading.

135. MANUFACTURING DEFENDANTS had a reasonable duty of care to disclose the true facts regarding the safety of Reglan to physicians and their patients, pharmacists, and the generic metoclopramide industry.

136. Furthermore, MANUFACTURING DEFENDANTS had a duty to ensure that they had a reasonable basis for making the representations described above, to exercise reasonable care in making those representations, to accurately make those representations, and to not make misrepresentations.

137. MANUFACTURING DEFENDANTS breached that duty by failing to disclose important safety information regarding metoc1opramide' s risks and misrepresenting Reglan/metoclopramide's safety in literature distributed on the drug.

138. MANUFACTURING DEFENDANTS made such misrepresentations knowing that the Reglan/metoclopramide user reasonably relied on the accuracy of that information, that they would take action based upon it, that individuals would be put in peril by such action, and that those individuals would suffer physical harm as a result.

139. MANUFACTURING DEFENDANTS' breach of its duties proximately caused damages to Plaintiff. As a direct and proximate cause of MANUFACTURING DEFENDANTS' conduct, Plaintiff has suffered or will continue to suffer injury, harm, and economic loss as alleged herein, including a permanent and substantial physical disability, and expenses attributable to this disability. MANUFACTURING DEFENDANTS breached their duty with the understanding patients and physicians would rely upon such actions when choosing MANUFACTURING DEFENDANTS' drugs.

COUNT 9
BREACH OF UNDERTAKING SPECIAL DUTY

140. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

141. At all relevant times, MANUFACTURING DEFENDANTS voluntarily undertook a duty to comply with the provisions set forth in FDA regulations and requirements, including but not limited to, conducting post market safety surveillance and communicating any significant data regarding the adequacy and/or accuracy of its warnings to maintain accurate and adequate medical safety information in package inserts. MANUF ACTURING DEFENDANTS knew or should have known that these undertakings were necessary for the protection of Plaintiff and her physicians, and that Plaintiff and her physicians would and did rely upon MANUFACTURING

DEFENDANTS to exercise reasonable care to perform, and to fulfill, the undertakings set forth in FDA regulations and requirements.

142. At all relevant times, MANUFACTURING DEFENDANTS failed to exercise reasonable care in performing, and failed to fulfill, the undertakings assumed in FDA regulations.

143. As a direct and proximate result of MANUFACTURING DEFENDANTS' failure to exercise reasonable care in performing and its failure to fulfill the undertakings assumed in FDA regulations, Plaintiff has suffered and will continue to suffer injury, harm, and economic loss as alleged herein, including a permanent and substantial physical disability, and expenses attributable to this disability.

COUNT 10
FRAUD AND MISREPRESENTATION

144. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

145. MANUFACTURING DEFENDANTS misrepresented the soundness and reliability of their drug to physicians and the general public through promotional and marketing campaigns. It misrepresented that Reglan/metoclopramide was safe and effective when used as instructed, when, in fact, it was dangerous to the health of patients. MANUFACTURING DEFENDANTS continued these misrepresentations for an extended period of time, without disclosing material information.

146. MANUFACTURING DEFENDANTS took advantage of the limited opportunity Plaintiff had to discover their strategic and intentional concealment of the design, manufacturing, and safety defects in Reglan/metoclopramide.

147. At the time MANUFACTURING DEFENDANTS promoted the drug at issue as safe and/or effective, they did not have adequate proof upon which to base such representations, and in fact, knew or should have known that Reglan/metoclopramide was dangerous.

148. MANUFACTURING DEFENDANTS concealed these design, manufacturing, and safety defects from the public by withholding information pertaining to the inherent design, manufacturing and safety defects and high risks of a severe and permanent neurological condition relating to their Reglan/metoclopramide and presenting the drug as sound and reliable.

149. MANUFACTURING DEFENDANTS' intentional misrepresentations and omissions were made willfully, wantonly or recklessly to the Plaintiff to induce purchase of their drug over other drugs on the market.

150. MANUFACTURING DEFENDANTS knew or should have known of the high risk Plaintiff would encounter by unwittingly agreeing to ingest their defective drug.

151. MANUFACTURING DEFENDANTS failed to exercise reasonable care and competence in obtaining and/or communicating information regarding the safe use of Reglan/metoclopramide and otherwise failed to exercise reasonable care in transmitting information to Plaintiff, Plaintiff's physician, and the general public.

152. MANUFACTURING DEFENDANTS made these representations in the course of their business as designers, manufacturers, and distributors of the drug at issue despite having no reasonable basis for their assertion that these representations were true and/or without having accurate or sufficient information concerning these representations MANUFACTURING DEFENDANTS were aware that, without such information, it could not accurately make these representations.

153. At the time these representations were made, MANUFACTURING DEFENDANTS intended to induce Plaintiff and/or Plaintiff's physician to rely upon such representations.

154. Said representations were made with the intent to defraud and deceive Plaintiff and/or Plaintiff s physician and with the intent to induce Plaintiff and/or Plaintiff's physician to rely upon the statements and use of Reglan/metoclopramide.

155. Plaintiff and/or Plaintiff's physician, at the time the representations were made, were unaware of their falsity and believed them to be true. In reasonable reliance thereon by Plaintiff and/or Plaintiff s physicians used Reglan/metoclopramide, and as a result, Plaintiff has suffered, and will continue to suffer, injury, harm and economic loss alleged herein.

156. As a direct and proximate result of reliance upon MANUFACTURING DEFENDANTS misrepresentations, Plaintiff has suffered and will continue to suffer injury, harm, and economic loss as alleged herein, including a permanent and substantial physical disability, and expenses attributable to this disability.

COUNT 11
CONSTRUCTIVE FRAUD

157. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein

158. MANUFACTURING DEFENDANTS, while in possession of unique and pertinent information involving the safety and reliability of Reglan/metoclopramide, presented its drug as sound and failed to warn of the drugs inherent design, safety and manufacturing defects. MANUFACTURING DEFENDANTS suppressed this information and continued sales and marketing of their drug to the general public. MANUFACTURING DEFENDANTS knew or should have known Plaintiff had no

means, other than MANUFACTURING DEFENDANTS full, accurate, and objective disclosure, of obtaining the relevant information.

159. Through its unique knowledge and expertise regarding the affected nature of Reglan/metoclopramide and through its statements to physicians and their patients in advertisement, promotional materials, and other communications, MANUFACTURING DEFENDANTS professed and affirmed to Plaintiff its knowledge of the truth of the representation that the drug at issue was safe for its intended use and was free from design, safety and manufacturing defects.

160. MANUFACTURING DEFENDANTS misrepresentations and omissions were made intentionally to induce Plaintiff to purchase MANUFACTURING DEFENDANTS' drug in order to reap high profit margins.

161. MANUFACTURING DEFENDANTS' conduct took unconscionable advantage of its dominant position of kl1owledge, engaging in constructive fraud in its relationship with Plaintiff. Misled by this veil of fraud, Plaintiff reasonably relied on MANUFACTURING DEFENDANTS' representations.

162. As a result, Plaintiff has suffered and will continue to suffer injury, harm, and economic loss as alleged herein, including a permanent and substantial physical disability, and expenses attributable to this disability.

COUNT 12
FRAUD BY CONCEALMENT

163. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

164. MANUFACTURING DEFENDANTS knowingly concealed- from physicians serious and permanent side effects caused by taking Reglan/metoclopramide for long periods of time.

165. MANUFACTURING DEFENDANTS misrepresentations and omissions were made intentionally to induce Plaintiff to purchase MANUFACTURING DEFENDANTS' drug in order to reap the high profit margin relating to MANUFACTURING DEFENDANTS.

166. Plaintiff's physician, in reliance upon the information disseminated by the MANUFACTURING DEFENDANTS, and without knowledge of theundisc10sed and knowingly concealed facts, determined that the benefits of prolonged Reglan/metoclopramide therapy outweighed the risks for their patients and prescribed a prolonged course of therapy for Plaintiff with Reglan/metoc1opramide products.

167. MANUFACTURING DEFENDANTS' conduct took unconscionable advantage of its dominant position of knowledge, engaging in fraud by concealment in its

relationship with Plaintiff. Misled by this veil of fraud, Plaintiff reasonably relied on MANUFACTURING DEFENDANTS' representations.

168. As a result, Plaintiff has suffered and will continue to suffer injury, harm, and economic loss as alleged herein, including a permanent and substantial physical disability, and expenses attributable to this disability.

COUNT 13
VIOLATION OF THE OHIO CONSUMER SALES PRACTICES ACT

169. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

170. MANUFACTURING DEFENDANTS' conduct, actions, and/or omissions, individually and/or as agents one for the other, by and through their agents, servants, and/or employees, as set out in detail above, violate the Ohio Consumer Sales Practices Act, Ohio R.C. §1345.01 et seq.

171. MANUFACTURING DEFENDANTS' conduct, actions, and/or omissions, as set out in detail above, have been and continue to be inherently unfair, offensive to public policy, immoral, unethical, and oppressive.

172. MANUFACTURING DEFENDANTS' conduct, actions, and/or omissions, as setout in detail above, have been and continue to be repeated in Ohio.

173. MANUFACTURING DEFENDANTS' conduct, actions, and/or omissions, as set forth above, constitute unfair and/or deceptive trade practices and are capable of repetition, and in fact have been repeated by MANUFACTURING DEFENDANTS' on a regular basis.

174. MANUFACTURING DEFENDANTS' conduct was willful, and MANUFACTURING DEFENDANTS' knew or should have known that its conduct violated Ohio Consumer Sales Practices Act.

175. As a result of MANUFACTURING DEFENDANTS' actions, Plaintiff is entitled to actual damages, treble damages, and her attorneys' fees and costs.

COUNT 14
.INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

176. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the .same force and effect as if fully set forth herein.

177. Through intentional, reckless, and extreme conduct, MANUFACTURING DEFENDANTS knowingly denied Plaintiff adequate opportunity in measuring the level of risk related to MANUFACTURING DEFENDANTS'

Reglan/metoclopramide. By withholding information of known design and manufacturing defects and concealing those fatal problems, MANUFACTURING DEFENDANTS created a false sense of security for Plaintiff, who assumed reasonable safety with MANUFACTURING DEFENDANTS' drug.

178. MANUFACTURING DEFENTIANTS conduct of intentional omission, concealment, and failure to warn of the design and manufacturing defects caused Plaintiff to suffer injury, harm, and economic loss as alleged herein, including a permanent and substantial physical disability, and expenses attributable to this disability.

179. The injuries described above entitle Plaintiff to compensatory damages and equitable and declaratory relief, along with all appropriate damages according to proof.

V. DAMAGES

180. As a direct and proximate result of the acts and omissions of DEFENDANTS, Plaintiff ingested Reglan, which was causally related to and contributed to Plaintiff s development of the permanent neurological disorder known as Tardive Dyskinesia and Akathisia.

181. As a direct and proximate result of the acts and omissions of DEFENDANTS, Plaintiff has suffered extreme emotional distress, anguish, physical and mental suffering, loss of the ability to control Plaintiff's facial expressions, mouth, tongue and jaw, which has rendered Plaintiff physically incapacitated.

182. As a direct and proximate result of the acts and omissions of DEFENDANTS, Plaintiff experiences extreme embarrassment, shame, anguish, anxiety, and has a sustained a loss of enjoyment of life.

183. Plaintiff seeks the recovery for past and future special damages, which includes medication, doctor, rehabilitation, therapy, and other assisted living and nursing care and Plaintiff also seeks general damages in the amount to be determined for the wrongful conduct of each separate and individual Defendant.

184. The acts and/or omissions of the MANUFACTURING DEFENDANTS were in heedless and reckless disregard of the rights, welfare, safety and well-being and involved such an entire want of care to indicate that such amounts to conscious and willful indifference, gross negligence and malice for which Plaintiff seeks recovery of actual and punitive damages.

185. As a direct and proximate result of the MANUFACTURING DEFENDANTS' negligence, gross negligence, willfulness, wantonness, recklessness, malice, or intentional conduct specified herein, underwent great shock and suffering, great physical pain and anguish, loss of enjoyment of life, diminished joys and pleasures.

186. Consequently, Plaintiff asserts a claim for judgment and seeks actual and punitive damages against each separate MANUFACTURING DEFENDANT in an amount to be determined by a jury, plus costs and any such other relief, in an amount sufficient to deter such unconscionable and irresponsible conduct in the future.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief against MANUFACTURING DEFENDANTS as follows:

1. The amount in controversy exceeds the jurisdictional requirement set forth in the Ohio Rules of Civil Procedure;

2. For judgment for damages sufficient to compensate Plaintiff for damages, including but not limited to past, present, and future economic expenditures;

3. For compensatory damages according to proof;

4; For all applicable statutory remedies provided by law in Ohio that assert liability for MANUFACTURING DEFENDANTS' wrongdoings and improper conduct;

5. For a disgorgement of profits;

6. For prejudgment interest, as permitted .by law;

7. For punitive damages as to MANUFACTURING DEFENDANTS in an amount to be determined by a jury;

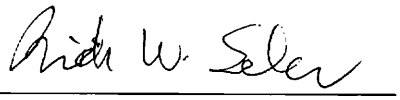
8. For reasonable costs, including attorneys fees as permitted by law; and

9. For all other just and proper relief.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

Respectfully submitted,



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